REMARKS/ARGUMENTS

Claims 2-8 are active.

Support for the amendment to Claim 2 is found on page 8, 1st paragraph and pages 11-12.

No new matter is added by the presentation of these claims.

The rejection based on Matsushita is respectfully traversed.

The Examiner has continued to reject the claims in view of Matsushita by asserting that the antibodies described by Matsushita inherently would bind to the specific peptide in the claims and that the active steps of Claim 2 do not distinguish from Matsushita's studies. However, it should be readily apparent that while Matsushita studies and discusses certain reactive epitopes of Pac that could be used for diagnostic tests (see page 4040, 2nd column, last paragraph), Matsushita does not describe examining caries risk by measuring the antibody titer of the secretory immunogloblin A (sIgA) and correlating that measurement to high or low risk caries. Moreover, there is nothing in Matsushita which discusses examining caries risk with an antibody directed against a peptide consisting of SEQ ID NO:1 as set forth in Claim 2 nor correlating the titer of the antibody in the human saliva to caries risk.

Accordingly, withdrawal of this rejection is requested.

The rejection under 35 USC § 112, second paragraph pertaining to the low and high determinations found in the claims is traversed. Notably, these terms are relative to the caries risk and antibody titers and therefore are clear. Withdrawal of the rejection is requested.

The Examiner has also rejected the claims based on the lack of description or enablement for a labeled antibody. Based on the discussion in the current specification (see pages 11-12), the claims have been amended to define that the measuring step in the claim

comprises determining the secretory immunoglobulin A with a labeled antibody. Therefore, it is clear that the specification describes how to determine an antibody titer with a labeled antibody. In a similar manner the rejection of Claims 2-8 under 35 USC 112, first paragraph (pages 4-5 of the Official Action) is no longer applicable as how the antibody titer is measured has been clarified consistent with the specification (pages 11-12).

Withdrawal of both rejections is requested.

The rejection that the claimed method as not enabled is also traversed. This rejection is substantially similar to the rejection the Examiner raised in the first Official Action. The Examiner has taken the position that the method defined in the claim is not predicative of dental caries because determining a single time point of reactivity does not correlate with caries risk. Applicants disagree and for the reasons discussed below, submit that the claimed method is enabled.

First, it should be noted that claim 2 includes the manner in which caries risk is assessed the relationship between the titer and caries risk as discussed throughout the specification (including the Examples).

As discussed on pages 5-6 of the specification there has been some recent studies that observed the presence of Pac on the surface of mutans streptococci and this was related to the initial adhesion of the mutans streptococci to the tooth surface. Therefore, if a person whose antibody titer against the antigen is high, there would be an indication that streptococci inhibition would be occurring meaning a lower relative risk of caries in that individual. However, it was subsequently found that the level of infection and the caries risk could not be adequately correlated. This was perhaps due in part to the presence of a human

immunoglobulin directed against an array of antigens on the surface of the mutans streptococci.

What the inventors found is that if they utilized a synthetic peptide having only the sequence in the region of 361-386 (denominated as SEQ ID NO:1 in this application), then the caries risk can be accurately examined in short time based on the initial adhesion of the mutans streptococci to the tooth surface. Indeed, the Examples presented in the specification show that this correlation exists.

Table 1 on page 20, shows antibody titers in saliva of five subjects (A, B, C, D, E) measured by ELISA assays. In this data set, the quantity of the mutans streptococci in saliva of subjects A, C, E in which antibody titers are high (high titer indicates an inhibition of the mutans streptococci at the tooth surface and therefore lower quantity of the streptococci) and as such the caries risk is relatively low. In contrast, in subjects B and D, the antibody titers are low meaning higher quantities of the streptococci and therefore higher relative risk of caries in those subjects. ) of which antibody titers are low (low inhibits of the mutans streptococci to the tooth surface).

In Table 2 on page 23, antibody titers were measured by Immuno-Chromatography. The data set presented here shows similar results to those in Table 1. Notably, the higher quantities of streptococci is indicative of a higher relative risk of caries.

Therefore, the data coupled with the description provided in the specification provides a reasonable correlation between antibody titers, streptococci quantities and relative risks of caries.

Withdrawal of this rejection is requested.

Allowance of the claims is requested.

Respectfully submitted,

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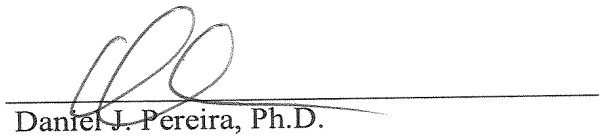

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